K024350

APR - 2 2003

7. SUMMARY OF 510(k)

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K024350.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Tel.: 858-535-2030
Fax: 858-535-2038

Establishment Registration Number: 2531491
Owner/Operator Number: 9033096

Date:

December 27, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® *H. pylori* Rapid Test Strip
ACON® *H. pylori* Rapid Test Device

Common Name:

Immunochromatographic test for the qualitative detection of IgG antibodies specific to *Helicobacter pylori (H. pylori).*

Classification Information:

The ACON® *H. pylori* Rapid Test Strip and Device are similar to other FDA-cleared devices for the qualitative detection of IgG antibodies specific to *H. pylori.*

Classification:	Class I
Regulation Number:	866.3110
Product Code:	LYR
Classification Name:	*Campylobacter pylori*
Complexity:	Moderate
Analyte:	IgG antibodies specific to *Helicobacter pylori* in human blood, serum or plasma
Test Category:	Manual procedures with limited steps and limited sample and reagent preparation

Intended Use:

The ACON® *H. pylori* Rapid Test Strip and Device are rapid chromatographic immunoassays for the qualitative detection of antibodies to *Helicobacter pylori* (*H. pylori*) in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older. They are intended for health professionals and professionals at point-of-care sites.

Description:

The ACON® *H. pylori rapid* Test Strip and ACON® *H. pylori rapid* Test Device are lateral flow immunochromatographic assays for the qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood, serum or plasma. They utilize *H. pylori* antigen coated particles and immobilized anti-human IgG to selectively detect elevated levels of IgG antibodies to *H. pylori.* These tests can be performed without the use of an instrument.

Comparison to Predicate Devices:

A summary of comparison of the features of the ACON® *H. pylori* Rapid Test Strip, ACON® *H. pylori* Rapid Test Device, and two predicate devices is shown below:

ACON *H. pylori* Tests versus Quidel QuickVue One-Step H. pylori gII (K991747)

Feature	ACON® *H. pylori* Rapid Test Strip	ACON® *H. pylori* Rapid Test Device	Quidel QuickVue One-Step H. pylori gII
Indication for use	A rapid chromatographic immunoassay for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood to aid in the diagnosis of *H. pylori* infection.	A rapid chromatographic immunoassay for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood to aid in the diagnosis of *H. pylori* infection.	A lateral-flow immunoassay intended for the qualitative detection of IgG antibodies specific to *Helicobacter pylori* in whole blood to aid in the diagnosis of *H. pylori* infection.
Intended Use	Professional	Professional	Professional
Intended specimen	Whole blood, serum, plasma	Whole blood, serum, plasma	Whole blood, serum, plasma
Endpoint	Colored Lines	Colored Lines	Colored Lines
Materials provided	Test strips Disposable sample test tubes Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test devices Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test devices Disposable droppers Capillary tube Positive control Negative control Direction insert Procedure card Package Insert
Methodology	Membrane particle assay	Membrane particle assay	Membrane particle assay
Test Time	10 minutes	10 minutes	5 minutes
Format	Antigen/antibody immunoassay	Antigen/antibody immunoassay	Antigen/antibody immunoassay

ACON *H. pylori* Tests versus Beckman Coulter FlexSure HP (K934863)

Feature	ACON® *H. pylori* Rapid Test Strip	ACON® *H. pylori* Rapid Test Device	Beckman Coulter FlexSure HP
Indication for use	A rapid chromatographic immunoassay for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood to aid in the diagnosis of *H. pylori* infection.	A rapid chromatographic immunoassay for the qualitative detection of antibodies to *Helicobacter pylori* in whole blood to aid in the diagnosis of *H. pylori* infection.	A rapid, visually read, qualitative immunochromato-graphic method for the detection of IgG antibodies to H. pylori in serum as an aid in the diagnosis of H. pylori infection in patients with clinical signs and symptoms of gastrointestinal disease is not intended for use with asymptomatic patients.
Intended Use	Professional	Professional	Professional
Intended specimen	Whole blood, serum, plasma	Whole blood, serum, plasma	Serum
Endpoint	Colored Lines	Colored Lines	Colored Lines
Materials provided	Test strips Disposable sample test tubes Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test devices Disposable droppers Capillary tube Dispensing bulb Positive control Negative control Buffer Package insert Procedure card	Test cards Disposable transfer pipettes Capillary tube Buffer Product Instructions
Methodology	Membrane particle assay	Membrane particle assay	Membrane particle assay
Test Time	10 minutes	10 minutes	4 minutes
Format	Antigen/antibody immunoassay	Antigen/antibody immunoassay	Antigen/antibody immunoassay

Accuracy

A clinical evaluation was conducted using a total of 484 clinical specimens. The detection of *H. pylori* specific antibodies was done by using the ACON® *H. pylori* Rapid Test Strip and Test Device, Quidel QuickVue One-Step H. pylori gII Test and Beckman FlexSure HP Test.

ACON® *H. pylori* Rapid Test Strip compared to Quidel QuickVue One-Step H. pylori gII Test

Positive Agreement = 92/104 = 88% (81%-94%)*
Negative Agreement = 89/96 = 93% (86%-97%)
Overall Agreement = 181/200 = 90% (86%-94%)
* 95% Confidence Intervals

ACON® *H. pylori* Rapid Test Strip compared to Beckman Coulter FlexSure HP

Positive Agreement = 61/68 = 90% (80%-96%)
Negative Agreement = 93/95 = 98% (92%-100%)
Overall Agreement = 154/163 = 94% (90%-97%)

ACON® *H. pylori* Rapid Test Strip compared to Culture/Histology:

Sensitivity = 120/136 = 88% (82%-93%)
Specificity = 164/185 = 89% (83%-93%)
Accuracy = 284/321 = 88% (84%-92%)

ACON® *H. pylori* Rapid Test Strip compared to Histology/Rapid Urease Test:

Sensitivity = 50/71 = 70% (58%-81%)
Specificity = 79/92 = 86% (77%-92%)
Accuracy = 129/163 = 79% (72%-85%)

ACON *H. pylori* Rapid Test Device compared to Quidel QuickVue One-Step H. pylori gII Test

Positive Agreement = 92/104 = 88% (81%-94%)
Negative Agreement = 89/96 = 93% (86%-97%)
Overall Agreement = 181/200 = 90% (86%-94%)

ACON *H. pylori* Rapid Test Device compared to Beckman Coulter FlexSure HP Test

Positive Agreement = 67/68 = 98% (92%-100%)
Negative Agreement = 94/95 = 99% (94%-100%)
Overall Agreement = 161/163 = 99% (96%-100%)

ACON *H. pylori* Rapid Test Device compared to Culture/ Histology:

Sensitivity = 121/136 = 89% (82%-94%)
Specificity = 164/185 = 89% (83%-93%)
Accuracy = 285/321 = 89% (85%-92%)

ACON *H. pylori* Rapid Test Device compared to Histology/Rapid Urease Test

Sensitivity = 52/71 = 73% (61%-83%)
Specificity = 76/92 = 83% (73%-90%)
Accuracy = 128/163 = 78% (71%-84%)

Conclusion:

Clinical and laboratory studies included in this 510(k) submission demonstrate that the ACON *H. pylori* Rapid Test Strip and Test Device are substantial equivalent to the Quidel QuickVue One-Step H. pylori gII Test and the Beckman Coulter FlexSure HP which are already marketed in the U. S. They further demonstrate that these ACON *H. pylori* rapid test products are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 2 2003

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, CA 92121

Re: k024350
Trade/Device Name: ACON® *H. pylori* Rapid Test Strip
ACON® *H. pylori* Rapid Test Device
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: December 27, 2002
Received: December 30, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

9. INDICATIONS FOR USE

510(k) Number: K024350

Device Name: ACON® *H. pylori* Rapid Test Strip

ACON® *H. pylori* Rapid Test Device

Indications for Use: The ACON® *H. pylori* Rapid Test Strip and ACON® *H. pylori* Rapid Test Device are rapid chromatographic immunoassays for the qualitative detection of antibodies specific to *H. pylori* in human whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older. They are intended for healthcare professionals and professionals at point of care sites only.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____